

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

IN RE: PHILIPS RECALLED CPAP, BI-)	
LEVEL PAP, AND MECHANICAL)	Master Docket: Misc. No. 21-1230
VENTILATOR PRODUCTS)	
LITIGATION,)	MDL No. 3014
)	
This Document Relates to:)	(Oral Argument Requested)
)	
<i>Second Amended Master Long Form</i>)	
<i>Complaint for Personal Injuries and</i>)	
<i>Damages, and Demand for Jury Trial (ECF</i>)	
<i>No. 2505 / 2511 (under seal))</i>)	

**PLAINTIFFS' BRIEF IN OPPOSITION TO PHILIPS RS
NORTH AMERICA LLC'S MOTION TO DISMISS PURSUANT
TO FEDERAL RULES OF CIVIL PROCEDURE 12(b)(1) AND 12(b)(6)**

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I. INTRODUCTION

In its January 24, 2024 Opinion, the Court granted leave for Plaintiffs to amend their master personal injury complaint (ECF 834) (“Prior Complaint”). ECF 2471 (“Opinion” or “Op.”) at 17-18.¹ The Court gave clear instructions that any amendments were to be limited to the discrete issues raised in the prior motions practice,² that the new pleading should reflect the issues that were previously decided, and that any motion to dismiss the amended complaint should be limited to the revised or supplemented portions of the new complaint. *Id.* at 6-7. Consistent with that direction, on February 12, 2024, Plaintiffs filed the Second Amended Master Long Form Complaint for Personal Injuries (ECF 2505) (“Complaint”).³ On March 11, 2024, Philips⁴ filed its pending Motion to Dismiss (ECF 2574) (“Motion”) making discrete arguments, most of which fail for the reasons set forth below. But Philips also raised several arguments for the first time. The Court should reject these new arguments because they go beyond the Court’s directive.

II. ARGUMENT

A. Plaintiffs’ Recall-Related Negligence Claims Are Not Preempted

Philips reasserts its argument that both recall-related claims—negligent failure to recall (Count VI(1)) and negligent (execution of the) recall (Count VI(2))—are preempted. Philips once again mischaracterizes these claims as “seek[ing] to enforce the Federal Food, Drug, and Cosmetic Act (“FDCA”)” or otherwise being rooted in noncompliance with related regulations. Br. at 1-3.

¹ See also ECF 2472 (“Order”); Special Master’s Report and Recommendation with respect to Defendant’s Motion to Dismiss the Master Personal Injury Complaint (ECF 2271) (the “R&R”).

² Prior briefing on this matter includes, among other things: Philips’ Motion to Dismiss the Prior Complaint (ECF 1346) (“Philips’ Orig. Br.”); Pls’ Opp. thereto (ECF 1643) (“Pls’ Orig. Opp.”); Philips Reply thereto (ECF 1728); Philips’ Obj. to the R&R (ECF 2315) (“Philips Obj.”).

³ See also ECF 2511 (unredacted). “¶” citations are to the Complaint unless otherwise noted.

⁴ “Philips” refers to Defendant Philips RS North America LLC. “Other Philips Defendants” refers to Philips entities other than Defendant Philips RS North America LLC.

But, as discussed below, these claims are rooted in Philips’ breach of traditional state law duties thus avoiding any issues arising from *Buckman*.⁵ See, e.g., *Bausch v. Stryker Corp.*, 630 F.3d 546, 557 (7th Cir. 2010) (distinguishing state law duties from fraud-on-the-FDA theory in *Buckman*).

“Preemption is an affirmative defense that the defendant has the burden to prove.” *In re Allergan Biocell Textured Breast Implant Prods. Liab. Litig.*, 537 F. Supp. 3d 679, 705 (D.N.J. 2021) (citation omitted). Moreover, there is a presumption against preemption in areas where states have traditionally exercised their powers, including “matters of health and safety.” *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 771 (3d Cir. 2018) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)). “[T]he historic police powers of the States [a]re not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.” *Lohr*, 518 U.S. at 485.

Here, Philips invokes implied conflict preemption.⁶ Br. at 2. Conflict preemption only applies in two circumstances: (1) when it is “*impossible* for a private party to comply with both state and federal requirements” (impossibility preemption), or (2) where the state law “stand[s] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress” (obstacle preemption). See *Binakonsky v. JM Brands, Inc.*, 2022 WL 2757674, at *2 (W.D. Pa.

⁵ *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 349 (2001). *Buckman* is not determinative here because neither recall-related claim depends on violations of the FDCA and both are “viable even if the FDCA had never been enacted.” *O’Neil v. Somatics, LLC*, 2022 WL 4611938, at *6 (D.N.H. Sept. 30, 2022); compare *Buckman*, 531 U.S. at 353 (implied preemption for state claims that exist “solely by virtue of” federal law). For the same reasons, the Court already found that other of Plaintiffs’ claims arise from state law duties and do not depend on the federal statute. Op. at 4 n.5 (adopting R&R on preemption).

⁶ There are three types of preemption: express preemption, implied field preemption, and implied conflict preemption. See *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 334 (3rd Cir. 2009). Express preemption does not apply because devices that went through the streamlined § 510(k) approval process rather than a formal pre-market approval (“PMA”) “do not receive the benefit of express preemption.” *Shuker*, 885 F.3d at 767 (citing *Lohr*, 518 U.S. at 492-94). In addition, implied field preemption is not implicated. See, e.g., *Lohr*, 518 U.S. at 508 (finding no indication of intent for “the relevant FDA regulations to occupy entirely any relevant field.”). Indeed, the statute’s own savings clause demonstrates the field is not wholly occupied. 21 U.S.C. § 360h(d).

July 14, 2022) (emphasis added); *see also Holk*, 575 F.3d 339. Neither applies here.⁷

Negligent Failure to Recall. Plaintiffs bring a negligent failure to recall claim alleging that there are state law duties requiring Philips, “[a]s the designer, manufacturer, marketer, and/or seller of the Recalled Devices,” to recall the devices once it knew of the defect and its associated health risks. ¶ 423; *see also* ¶¶ 413-427. Indeed, Philips did not challenge the viability of negligent failure to recall as a claim in the majority of jurisdictions, Orig. Br. at 18 (challenging only 10 jurisdictions), and that is because the existence of this independent state law duty is widespread. *See, e.g.,* California JCC Civil Jury Instruction 1223 (jury instructions for negligent recall without reference to regulation); *In re Pac. Fertility Ctr. Litig.*, 2021 WL 5161926, at *2 (N.D. Cal. Nov. 5, 2021). FDA regulations permit Philips to launch a recall “of its own volition and under any circumstances.” *See* 21 C.F.R. § 7.46. Simply put, Philips could have easily complied with both federal and state requirements so “impossibility” preemption does not apply.

In assessing “obstacle” preemption, courts look to whether the state law (here the imposition of a duty to recall) “stood as an ‘obstacle’ to the accomplishment’ of a significant federal regulatory objective.” *Williamson v. Mazda Motor of Am.*, 562 U.S. 323, 330 (2011) (citation omitted). Here, the stated objective of the “Firm-initiated recall” regulation is to give

⁷ Analysis in prior briefing discussed a “narrow gap” that claims must fit into to avoid preemption. That gap, however, incorporates both express and implied preemption: (1) “[t]he plaintiff must be suing for conduct that violates the FDCA (*or else his claim is expressly preempted* by § 360k(a)),” and (2) “the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*).” *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (emphasis added). Because express preemption does not apply here, Plaintiffs’ claims only need to satisfy the latter criteria which, as discussed herein, they do. However, even if the Court considered whether the conduct complained of “violates the FDCA” (or is not “different from, or in addition to” federal regulations) under the first criteria, the recall-related claims would still satisfy the test. The relevant regulations acknowledge, consistent with state law duties, that manufacturers have a “responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective.” 21 C.F.R. § 7.40.

manufacturers an avenue “to carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective.” 21 C.F.R. § 7.40. State law duties that require a manufacturer to recall a product once it becomes aware of a harmful defect further the statutory objectives. Therefore, “obstacle” preemption does not apply. *E.g.*, *Williamson*, 562 U.S. at 336.

Negligent (Execution of the) Recall. Plaintiffs allege that “[i]n issuing a voluntary recall, Philips assumed duties to exercise reasonable care in issuing and implementing the Recall” and that they breached those duties. ¶ 438; *see also* ¶¶ 428-442. Philips has not challenged the viability of a negligent (execution of the) recall claim under any state’s law nor could it because these independent state law duties are widespread. *E.g.*, Restatement Third, Torts: Products Liability (4th ed.) § 6:26 (liability for damages caused by negligence in failing to act “as a reasonable person in recalling the product”). Instead, Philips argues these claims are impliedly preempted because they “encroach[] upon the FDA’s exclusive province” and notes that Plaintiffs cite “the FDA’s notification order under section 518(a) of the FDCA.” Br. at 2-3. But, the FDCA itself provides that state law liability actions can proceed alongside regulatory action and related orders, such as the 518(a) order. *See* 21 U.S.C. § 360h(d) (“Effect on other liability”: “Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law.”) Plaintiffs’ reference to FDA correspondence serves as evidence of Philips’ failure to exercise due care, not a backdoor attempt to enforce the FDCA. Philips’ argument should be rejected.

Philips previously dismissed the import of § 360h(d) claiming the Supreme Court had rejected its broad application. Orig. Reply at 8 n.7 (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008)). But Philips overreads *Riegel* which simply found that § 360h(d) does not mean *all* state law claims are preempted, otherwise it “would deprive the [express] pre-emption clause of all

content.” *Riegel*, 552 U.S. at 325 n.4. Here, where the express preemption provision of § 360k is not implicated, Philips’ attempt to render § 360h(d) a nullity should be rejected as it contradicts the express language of the statute and Congress’ intent to preserve certain state law claims specifically related to FDA’s involvement in a recall. *See generally Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1378-82 (11th Cir. 1999) (discussing the intersection of § 360k and § 360h(d)).

In addition, Plaintiffs’ allegations regarding the execution of the recall are entirely consistent with the FDA’s view of the recall. Put another way, once Philips informed the FDA about the recall and up to and including the time the Complaint was filed, Philips failed to act as a reasonable manufacturer should have to ensure the recall was rolled out effectively.⁸ *E.g.*, ¶¶ 301 & n.412, 433; *see also* ¶¶ 286-290, 300.⁹ Because of Philips’ negligence, Plaintiffs continued to use their defective devices and incur harms. Plaintiffs now seek only money damages for the harm they alone suffered as a result of that past negligence, ¶ 442, and are not asking the Court to oversee the recall or dictate how the recall is executed going forward.¹⁰

B. The Court Should Not Invoke Primary Jurisdiction Doctrine

Philips argues that the Court should *dismiss* Plaintiffs’ negligent (execution of the) recall claim under the primary jurisdiction doctrine. Br. at 3-6. It is well-established that federal courts

⁸ This renders this case different from *Cohen v. Subaru of Am., Inc.*, 2022 WL 721307, at *38 (D.N.J. Mar. 10, 2022). Unlike *Cohen*, which addressed a vehicle recall under a different statute, Plaintiffs are not questioning any regulatory action or suggesting additional regulatory action. *Gates v. Medtronic, Inc.*, 192 F. Supp. 3d 704 (W.D. Tex. 2016) is also misplaced because *Gates* involved express preemption where the device went through the PMA process. *Id.* at 708-09, 712.

⁹ Viewed through the lens of the impossibility preemption and obstacle preemption discussed above, Plaintiffs’ negligent (execution of the) recall claims are not preempted. It was possible for Philips to conduct a competent recall which would have complied with both state law duties and any guidance provided by the FDA. In addition, as discussed above, requiring a competent recall furthered the objectives of the FDA “Firm-initiated recall” policy, 21 C.F.R. §§ 7.40, 7.46.

¹⁰ Philips citation to *Nat’l Women’s Health Network, Inc. v. A. H. Robins Co.*, 545 F. Supp. 1177, 1180 (D. Mass. 1982), is inapposite. There, the plaintiff asked the court to order a worldwide recall.

should only abstain from exercising their jurisdiction in “exceptional cases” because they “have a ‘virtually unflagging obligation . . . to exercise the jurisdiction given them.’” *Baykeeper v. NL Indus., Inc.*, 660 F.3d 686, 691 (3d Cir. 2011) (citations omitted) (alteration in original). “The [primary jurisdiction] doctrine is a ‘prudential’ one, ‘under which a court determines that an otherwise cognizable claim implicates technical and policy questions that should be addressed in the first instance by the agency with regulatory authority . . . rather than by the judicial branch.’” *In re JUUL Labs, Inc., Mktg., Sales Pracs., and Prod. Liab. Litig.*, 497 F. Supp. 3d 552, 579 (N.D. Cal. 2020) (citation omitted). It is “reserved for a ‘limited set of circumstances’ that ‘requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency.’” *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 760 (9th Cir. 2015) (quoting *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008)). Philips cannot establish that circumstances warrant application of the primary jurisdiction doctrine here.

Most importantly, courts typically refrain from applying the primary jurisdiction doctrine in cases like this one where Plaintiffs seek only money damages. *See Philips v. Ford Motor Co.*, 2016 WL 693283, at *11-12 (N.D. Cal. Feb. 22, 2016) (no primary jurisdiction where plaintiff seeks money damages that cannot be provided by agency); *see also Ryan v. Chemlawn Corp.*, 935 F.2d 129, 131 (7th Cir. 1991) (same); *In re Recalled Abbott Infant Formula Prods. Liab. Litig.*, 2023 WL 3585759, at *7 (N.D. Ill. May 22, 2023) (same); *In re Methyl Tertiary Butyl Ether (“MTBE”) Prod. Liab. Litig.*, 175 F. Supp. 2d 593, 618 (S.D.N.Y. 2001) (“courts generally do not defer jurisdiction where plaintiffs seek damages for injuries to their property or person.”).

In addition, courts refrain from applying primary jurisdiction where the delay occasioned by abstention would be costly and inefficient. *See, e.g., White v. Beech-Nut Nutrition Co.*, 2024 WL 194699, at *2 (2d Cir. Jan. 18, 2024) (declining to weigh primary jurisdiction factors where

“any advantages of deferring to the FDA . . . are outweighed by the potential costs resulting from the delay in administrative proceedings”); *In re Trader Joe’s Co. Dark Chocolate Litig.*, 2024 WL 1319725, at *15 (S.D. Cal. Mar. 27, 2024) (no primary jurisdiction because of delay). Here, Philips asks the Court to *dismiss* Plaintiffs’ negligent (execution of the) recall claims for money damages. But there is no reason to foreclose Plaintiffs’ access to justice in this way. A review of the four-factor test set forth in *Global Naps, Inc. v. Bell Atl.-N.J., Inc.*, 287 F. Supp. 2d 532, 549 (D.N.J. 2003), and repeated in *Baykeeper*, while unnecessary here, illustrates that abstention on primary jurisdiction grounds is inappropriate. *See, e.g.*, R&R at 23-28.

Factors 1 & 2. The negligent (execution of the) recall claim does not require specific expertise. There is nothing particularly complex about assessing whether Philips exercised appropriate care in its work to execute the recall, and no reason to think it strays beyond a court’s normal range of competence. *Baykeeper*, 660 F.3d at 691; *In re Valsartan, Losartan, and Irbesartan Prods. Liab. Litig.* (“Valsartan”), 2020 WL 7418006, at *12 (D.N.J. Dec. 18, 2020) (review of relevant scientific and technical data not outside a court’s normal range of competence).¹¹ Nor is the negligent (execution of the) recall claim particularly within the agency’s discretion as the very statute governing the FDA’s oversight of the recall specifically contemplates parallel judicial action for state liability. 21 U.S.C. § 360h(d).

Factors 3 & 4. There is no risk of inconsistent rulings. Plaintiffs do not seek to undermine any action taken by the FDA nor do they seek a forward-looking remedy that conflicts with an FDA order. *Baykeeper*, 660 F.3d at 692. The FDA’s ongoing review of the recall alone does not overcome the other factors weighing against abstention. *Cohen*, 2022 WL 721307, at *37

¹¹ Philips points to 21 C.F.R. § 7.42(a), but this regulation doesn’t discuss “technical and policy considerations” that are uniquely within the FDA’s expertise, it discusses the elements a firm should consider in its recall “strategy.”

(initiation of recall “insufficient to justify abstention”). Primary jurisdiction is not appropriate here.

C. Negligent Failure to Recall Is Proper Under Illinois and Oklahoma Law

Illinois and Oklahoma recognize negligent failure to recall claim in circumstances like those here. R&R at 37-38; *Smith v. BOC Grp. PLC*, 2001 WL 477237, at *5 (N.D. Ill. May 4, 2001); *In re Gen. Motors LLC Ignition Switch Litig.*, 154 F. Supp. 3d 30, 37-41 (S.D.N.Y. 2015) (Oklahoma).

D. Negligence *Per Se* Is Viable in Delaware, Oregon, and Wisconsin

Philips challenges Plaintiffs’ negligence *per se* claim under Delaware, Oregon, and Wisconsin law.¹² Philips did not previously challenge the Delaware claim and thus waived this argument. *See* R&R at 40 n.8; Orig. Br., Table G(1). On the merits, these states recognize a claim for negligence *per se*. *E.g.*, *Price v. Blood Bank of Delaware, Inc.*, 790 A.2d 1203, 1212-13 (Del. 2002); *Phelps v. Wyeth, Inc.*, 938 F. Supp. 2d 1055, 1075-76 (D. Or. 2013); *Kurer v. Parke, Davis & Co.*, 679 N.W.2d 867, 874-76 (Wis. Ct. App. 2004).¹³

E. State Product Liability Act (“PLA”) Claims

1. Philips’ Subsumption Arguments Fail

Indiana. Plaintiffs’ breach of warranty claims (Counts X-XII) are not subsumed by the Indiana PLA. The IPLA “has been found to subsume neither claims of violation of state consumer protection statutes nor claims of breach of express warranty or implied warranty.” *Valsartan*, 2021 WL 364663, at *13 (D.N.J. Feb. 3, 2021). If the Court finds these claims subsumed, they should be considered a legal theory included in Count XXIV. ¶ 1743.

Fraud Claims Under the Ohio PLA. Fraud claims in a personal injury context are not

¹² Rhode Island does not permit a separate cause of action for negligence *per se*.

¹³ Philips’ cases, Br. at 6 n.5, do nothing more than stand for the proposition that invoking negligence *per se* does not obviate the need for plaintiff to establish causation and damages.

subsumed by the OPLA.¹⁴ Ohio Rev. Code § 2307.72(A) & (B); *Valsartan*, 2021 WL 364663, at *17; *Hollar v. Philip Morris Inc.*, 43 F. Supp. 2d 794, 808 (N.D. Ohio 1998).¹⁵ If the Court finds fraud is subsumed, it should be considered a legal theory being asserted in Count XXIX. ¶ 1834.

Statutory Claims Under the Indiana, Mississippi and New Jersey PLAs. Philips argues that statutory consumer protection claims for Indiana (Count XVI(14)), Mississippi (Count XVI(22)), and New Jersey (Count XVI(27)) are subsumed. Philips did not object to the Special Master’s finding that the IPLA does not subsume this claim and thus, has waived the argument. Op. at 4-5, 7; R&R at 31. Even if not waived, the R&R was correct on this point. *See Valsartan*, 2021 WL 364663, at *13 (citing *Fowler v. Werner Co.*, 2014 WL 2605341, at *1 (N.D. Ind. June 10, 2014)). The MPLA likewise does not “preclude other statutory causes of action.” *Id.* at *16. And, the NJPLA does not bar claims based on “deceptive, fraudulent, misleading, and other unconscionable commercial practices.” *See Sun Chem. Corp. v. Fike Corp.*, 235 A.3d 145, 156 (N.J. 2020). If the Court finds these claims are subsumed, they should be considered as theories asserted under each state’s PLA—Counts XXIV, XXVII, and XXVIII. ¶¶ 1743, 1795, 1812.

2. Philips’ Attack on Single Theories Within a PLA Should be Denied

Philips’ argument that the theories for four state PLAs are too inclusive does not support dismissal. Br. at 8. Philips concedes that Plaintiffs allege multiple permissible theories for each claim yet seeks dismissal (or to “strike” certain theories). Philips does not identify which theories to strike or supporting case law and the Court should reject this argument out of hand. *See Brackbill v. Ruff*, 2018 WL 2322014, at *6 (M.D. Pa. May 22, 2018) (declining to address undeveloped

¹⁴ Plaintiffs do not contest that Fraud claims (Count XIII) are subsumed under the Kansas, Mississippi, and Tennessee PLAs but the Court should consider these claims as theories asserted under each state’s PLA—Counts XXV, XXVII, and XXX. ¶¶ 1760, 1795, 1850.

¹⁵ *McFarland v. Ethicon, Inc.*, 2020 WL 4464401, at *2 (S.D. Ohio, Aug. 4, 2020), cited by Philips, Br. at 7 n.8, is inapposite because the subsumption argument was not addressed by the plaintiff.

argument). In any event,, Philips’ attempt to use Rule 12(b)(6) to dismiss only part of a claim is impermissible. *Redwind v. W. Union, LLC*, 2019 WL 3069864, at *4 (D. Or. June 21, 2019) (collecting cases), *report and recommendation adopted*, 2019 WL 3069841 (D. Or. July 12, 2019). Dismissal is unwarranted even if, as Philips contends, Plaintiffs’ theories are overinclusive.

F. Plaintiffs’ Fraud Claims Are Properly Plead

Philips’ challenge to Plaintiffs’ fraud claims (Count XIII) addresses only to whether there was a “duty to disclose” and only applies to 13 states.¹⁶ Br. at 8. The parties have previously fully briefed this issue and Philips cursory argument here offers nothing new. As Plaintiffs previously explained, there are three exceptions to the general rule that a duty to disclose exists only when the parties have a confidential or fiduciary relationship: (1) where one party has superior knowledge; (2) when the defect at issue goes to health and safety; and/or (3) where the defendant makes a partial or ambiguous disclosure while concealing other relevant information. *See* Pls. Chart 7 (ECF 1643, at A-7). While Plaintiffs plead all three exceptions and supporting facts (¶¶ 562-63; *see also, e.g.,* ¶¶ 132-236), in 4 of the states at issue (Maryland, Ohio, Oregon, South Dakota), the only applicable exception is the “partial disclosure” exception.¹⁷

¹⁶ Arkansas, Florida, Georgia, Illinois, Maryland, Massachusetts, Mississippi, Nevada, Ohio, Oregon, Pennsylvania, South Dakota, and Virginia. The Special Master addressed this argument in the context of negligent misrepresentation for 11 of the 13 states and found that in 10 states, there was a duty to disclose. R&R at 62-75. In the 1 remaining state, South Dakota, the Special Master relied on a case, *Taggart v. Ford Motor Credit Co.*, 462 N.W.2d 493, 504 (S.D. 1990), that acknowledges a duty to disclose arising from a partial disclosure. *See also Ducheneaux v. Miller*, 488 N.W.2d 902, 909 (S.D. 1992).

¹⁷ Philips’ footnote 14 mirrors, with 2 exceptions, the table appended to its Original Brief. These cases do not contest the exceptions argued here. *Compare* Op. Br. (ECF 1246) at Citation Table E(2)(a) *with* Plaintiffs’ Orig. Opp. at Chart 7 (ECF 1643 at A-7). The same is also true for Philips’ two new cases. *Compare Las Vegas Metro Police Dep’t v. Harris Corp., M/A Com, Inc.*, 2015 WL 895054, at *7 (D. Nev. Mar. 3, 2015) (Nevada law) (no partial disclosure occurred) *with Northern Nevada Mobile Home Brokers v. Penrod*, 610 P.2d 724, 727 (Nev. 1980) (party has a duty to disclose once information is provided) and *Gaines v. Krawczyk*, 354 F. Supp. 2d 573, 586 (W.D. Pa. 2004) (Pennsylvania law) *with North Penn Towns, LP v. Concert Golf Partners, LLC*, 2021

Plaintiffs explicitly plead the “partial disclosure” exception and the facts to support it. *E.g.*, ¶¶ 564; *see also, e.g.*, ¶¶ : ¶¶ 86, 235-247, 549-554. At the motion to dismiss stage, this is enough. Realizing the “partial disclosure” exception defeats their Motion, Philips crafts a misguided argument that pleading fraudulent misrepresentation is a prerequisite to invoking the “partial disclosure” exception. Br. at 8 n.13. The rationale for imposing a duty to disclose in these circumstances is that “once a party has undertaken to mention a relevant fact to the other party it cannot give only half of the truth.” *Brass v. Am. Film Tech., Inc.*, 987 F.2d 142, 150 (2d Cir. 1993) (citing *Junius Constr. Corp. v. Cohen*, 400, 178 N.E. 672 (N.Y. 1931) (Cardozo, J.)). Requiring, as Philips suggests, that the partial or ambiguous statement rise to the level of an actionable fraudulent misrepresentation would render the “partial statement” exception meaningless, undercut its purpose, and allow such “half-truths” to go unchecked.

G. Plaintiffs’ Consumer Protection Claims¹⁸

1. Prescription Medical Devices are “Consumer Goods”

The Special Master has issued a well-reasoned 13-page analysis rejecting Philips’ argument that the Recalled Devices are not “consumer goods” under the relevant statutes. R&R at 92-105; *see also* Orig. Br. at 35 & n.45, Table F(7); Pls.’ Orig. Opp. at 35-36 & Chart 15; Orig. Reply at 20. The Special Master’s analysis exceeded that of the parties in the prior briefing and there is no reason to disturb his findings.¹⁹ Philips repeat of this argument under the laws of sixteen states (Br. at 10-13) should fail again here for the same reasons.

WL 3562849, at *27 (E.D. Pa. Aug. 12, 2021) (listing where duty to speak).

¹⁸ Plaintiffs’ do not contest Philips’ arguments with respect to the North Dakota DTPA (Count XVI(31)) and the Utah Sales Practices Act (Count XVI(37)). Br. at 9.

¹⁹ The Special Master found against Philips for all states that were analyzed. Kentucky and Illinois law were not analyzed on this issue, but such an analysis should produce the same result.

Having lost on this issue, Philips attempts to co-opt the Court’s pronouncements regarding an appropriate *Erie* analysis in the medical monitoring context to suggest that performing routine legal analysis regarding terms in an existing statute would be “expanding” state law. Br. at 10-11 & n.18. Unlike the question of whether a state’s highest court would recognize a new previously unrecognized common law cause of action, the issue facing the Court here is much more straightforward: whether the Recalled Devices fit within the definition of a governing state statute. This is not a problem requiring *Erie* analysis.

Philips claims that the “R&R assumed the devices were ‘consumer goods’ under the laws of any state that lacks caselaw expressly holding that prescription medical devices are not ‘personal, household, or family’ goods.” Br. at 10. But, the Special Master did no such thing, instead analyzing the statutory language that Philips continues to ignore—language that highlights the broad scope of these statutes; and citing and relying upon analogous cases applying these statutes including those finding prescription drugs are “consumer goods.” R&R at 92-105. The R&R recognized that prescription drugs are a *much closer analogy* to the Recalled Devices than a surgical implant, surgical tool, or dental fillings; the key distinction being the Recalled Devices are sold to the user as the consumer whereas the surgical items are sold to the surgeon or dentist.²⁰

Philips correctly recites the definition of a “consumer,” but then concludes, without authority, that any item that is “prescribed” is “not available for consumer purchase” even though cases have applied these same statutes to prescription drugs.²¹ *E.g., In re Bextra & Celebrex Mktg.*

²⁰ Philips’ reliance on surgical implant cases is misplaced. *See, e.g., Otis-Wisher v. Medtronic, Inc.*, 616 F. App’x 433, 435 (2d Cir. 2015) (R&R at 101); *Hogan v. Md. State Dental Ass’n*, 843 A.2d 902, 906 (Md. App. 2004) (dental fillings not selected by consumers but practitioner).

²¹ Philips raises three arguments in support of its position that the Recalled Devices are not “consumer goods”—“restricted prescription-based distribution, FDA regulation, and the absence of a direct seller-consumer relationship (it is the physician who decides what therapy is appropriate and what device to prescribe).” Br. at 10. All three apply with equal force to prescription drugs.

Sales Practices & Prod. Liab. Litig., 495 F. Supp. 2d 1027, 1032-37 (N.D. Cal. 2011). The truth (and what must be accepted on the pleadings) is that, like prescription drugs from a pharmacy, consumers can purchase the Recalled Devices from numerous sources of their own choosing. *E.g.*, ¶¶ 240, 290, 550-51.

The broad language of the statutes is intended to be applied liberally to promote the purposes of protecting consumers against unfair and deceptive business practices. *See, e.g., Wang v. Massey Chevrolet*, 118 Cal. Rptr. 2d 770, 778 (Cal. Ct. App. 2002); *see also* Orig. Br., Table F(7). There is no language in these statutes that excludes the Recalled Devices as “consumer goods.” Philips does not meaningfully analyze the law of any state, and only cites cases addressing 4 of the 16 statutes.²² Philips otherwise highlights five cases construing the federal Magnuson-Moss Warranty Act (“MMWA”). These cases are inapposite, as they address the interplay of the MMWA with the federal Consumer Product Safety Act which—unlike the state statutes at issue here—specifically carves out “drugs, devices, or cosmetics.” *E.g., Forcellati v. Hyland’s, Inc.*, 876 F. Supp. 2d 1155, 1164-66 (C.D. Cal. 2012);²³ *Kanter v. Warner-Lambert Co.*, 122 Cal. Rptr. 2d 72, 85-86 (Cal. Ct. App. 2002); *In re Minnesota Breast Implant Litig.*, 36 F. Supp. 2d 863, 876 (D. Minn. 1998); *Goldsmith v. Mentor Corp.*, 913 F. Supp. 56, 63 (D.N.H. 1995); *Kemp v. Pfizer*, 835 F. Supp. 1015, 1024-25 (E.D. Mich. 1993).

²² Philips’ cases do not help its cause. *See, e.g., De Bouse v. Bayer*, 922 N.E.2d 309, 317-18 (Ill. 2009) (answering question of “whether offering prescription drugs for sale in Illinois is a representation that the drug is safe for its intended use”); *Lightner v. Medtronic, Inc.*, 2021 WL 4731351, at *7 (C.D. Cal. May 10, 2021) (construing California’s Song-Beverly Warranty Act); *Reeves v. PharmaJet, Inc.*, 846 F. Supp. 2d 791, 798 n.2 (N.D. Ohio 2012) (flu shot injector). The Special Master correctly explains why Philips is wrong about the Alabama, Maryland and West Virginia cases it cites. R&R at 93, 97 & 103.

²³ If anything, *Forcellati* supports Plaintiffs. It recognizes the differences between personal use drugs and surgical implants, and holds that the defendants had not “engaged in a sufficiently comprehensive analysis” of the statutes, which is even truer here. 876 F. Supp. 2d at 1165-66.

2. Omissions Can Support a Claim Under the Wisconsin DTPA

Courts have found that a Wisconsin DTPA claim can proceed when, analogous to a fraudulent omission, the defendant makes partial statements that are rendered misleading by the omission of known facts. *See In re General Motors LLC Ignition Switch Litig.*, 257 F. Supp. 3d 372, 456-57 (S.D.N.Y. 2017) (citing *Murillo v. Kohl's Corp.*, 197 F. Supp. 3d 1119, 1127 (E.D. Wis. 2016) and *Christense v. TDS Metrocom LLC*, 763 N.W.2d 248 n.4 (Wis. Ct. App. 2008)). As described in Section II.F, *supra*, Plaintiffs have alleged such partial statements here. Philips' challenge to an omissions theory under the Wisconsin DTPA (Count XVI(42)) therefore fails.

3. Pre-Suit Notice Was Satisfactory Here

Philips challenges presuit notice in five states and raises a related argument for Mississippi's informal dispute resolution requirement. Br. at 13-14. The original Master Complaint was filed on August 22, 2022, after Philips was on notice. ¶¶ 701 (CA), 955 (IN), 1056 (MA), 1155 (MS), 1632 (WV), 1683 (WY); *see also* Motion, Exs. A-D. In addition to providing notice, Plaintiffs plead numerous exceptions to presuit notice requirements. ¶¶ 701, 955, 1056, 1155, 1632, 1683. This notice, which occurred pre-Master Complaint, is sufficient. Requiring individual notice for individual short form complaints would defeat all of the efficiencies that have been established in this multidistrict litigation.

Philips' challenge to notice is really to the *form* of notice rather than receipt. *Compare* Mot. Ex. A *with* Mot. Ex. B and Mot. Ex. C *with* Mot. Ex. D. But, the sufficiency of notice is a fact question not appropriate for a motion to dismiss. *See Holtec Int'l v. ARC Machines, Inc.*, 492 F. Supp. 3d 430, 444 (W.D. Pa. 2020); R&R at 112-13.²⁴

²⁴ The Court asked the Parties to address "what constitutes 'presuit notice' in the context of a master complaint in an MDL." Op. at 7 n.8. Philips responds by arguing for dismissal of claims from the Master Complaint that individual plaintiffs could reassert if they provide notice that satisfies Philips, in a process that turns MDL practice on its head. Br. at 14 & n.28. This runs

4. The Alabama Deceptive Trade Practices Act Claim Is Not Waived

Plaintiffs can plead both Alabama DTPA and common law fraud claims in the alternative and elect which avenue to pursue later in the litigation under Federal Rule of Civil Procedure 8. *See, e.g., In re General Motors*, 257 F. Supp. 3d at 405-06; *Morris v. Walmart Inc.*, 2020 WL 470287, at *6 (N.D. Ala. Jan. 29, 2020).

5. Philips' New Rule 12(b)(1) Argument Must Fail

Philips asserts a standing argument under the consumer protection laws of ten states with a citation to a single case addressing one state's law (and citation to statutes with no interpretative case law for the remaining nine states). Br. at 15. This undeveloped argument, raised for the first time here, should be considered waived and/or rejected out of hand. Op. at 6-7; *Brackbill*, 2018 WL 2322014, at *6. On the merits, Philips' argument is misguided because it seeks dismissal of *some hypothetical plaintiffs* from claims that are otherwise valid. Br. at 15. That is improper for a motion to dismiss a master complaint that is not specific to any plaintiff.²⁵

III. CONCLUSION

For the foregoing reasons and those previously advanced, Plaintiffs respectfully request that the Court deny Philips' Motion.

contrary to the operative case management orders, PTO 26 (ECF 871) and PTO 28 (ECF 783), which established a streamlined process for, among other things, filing short-form complaints and exchanging plaintiff information and it does not mention individual notice.

²⁵ Philips bare citation to only statutes provides no insight into statutory interpretation and is insufficient. For example, Philips claims an action can only be brought by Colorado "consumers who 'purchased' a product." Br. at 15 n.31. But, case law makes clear that "the plaintiff need not be an actual or potential consumer of the defendant's product or service." *See NetQuote, Inc. v. Byrd*, 504 F. Supp. 2d 1126, 1135 (D. Colo. 2007).

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